

United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Permit to Move Live Plant Pests, Noxious Weeds, and Soil

Importation
Regulated by 7 CFR 330

This permit was generated electronically via the ePermits system

PERMITTEE NAME:	Dr. Frisby Smith	PERMIT NUMBER:	P526P-18-00844
ORGANIZATION:	Bayer US - Biologics	APPLICATION NUMBER:	P526-180213-005
ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	FACILITY NUMBER:	3279
MAILING ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	HAND CARRY:	No
PHONE:	916-661-3322	DATE ISSUED:	03/13/2018
FAX:		DATE AMENDED:	03/28/2018
DESTINATION:	890 Embarcadero Drive, West Sacramento, CA 95605	EXPIRES:	03/12/2021
DESIGNATED PORTS:	CA, El Segundo; CA, San Francisco; FL, Miami (Cargo, DHL, Fed Ex, UPS, etc); GA, Atlanta (Air Cargo Only - No Maritime shipments authorized); NJ, Linden; NY, Jamaica; TX, Humble; WA, SeaTac		

Under the conditions specified, this permit authorizes the following:

<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Bacteria	Microbial solutions, Mycelia, Petri dishes/culture tubes, Spores	Diagnostic Labs	Mexico, Germany	Originally Collected from Foreign Locations	FM-unk001 to 999, TL-unk001 to 999, BP-unk001 to 999
Fungi	Microbial solutions, Mycelia, Petri dishes/culture tubes, Spores	Diagnostic Labs	Mexico, Germany	Originally Collected from Foreign Locations	FM-unk001 to 999, TL-unk001 to 999, BP-unk001 to 999
Virus	Microbial solutions, Mycelia, Petri dishes/culture tubes, Spores	Diagnostic Labs	Mexico, Germany	Originally Collected from Foreign Locations	FM-unk001 to 999, TL-unk001 to 999, BP-unk001 to 999

SPECIAL INSTRUCTIONS TO INSPECTORS

See permit conditions below

INSTRUCTIONS TO DHS CBP INSPECTORS:

1. Confirm that the carrier of the shipment imported under this USDA PPQ 526 permit is commercially bonded. For all hand carry events, go to step 6. [THIS PERMIT DOES NOT AUTHORIZE HAND-CARRY OF THE REGULATED MATERIAL].

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Vickie Brewster
Vickie Brewster

DATE

03/28/2018

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2. Confirm that the imported shipment has a valid USDA PPQ Form 599 Red/White label attached to the exterior for routing to a USDA APHIS PPQ Inspection Station. (A valid label will have the permit number, expiration date, label number, and address of a USDA APHIS PPQ Plant Inspection Station)
3. Validate the permit in ePermits using the CBP search feature.
4. If a valid PPQ Form 599 Red/White label is not attached to the exterior of the package or the label has been covered or is otherwise not legible, then forward to the nearest USDA APHIS PPQ Plant Inspection Station.
5. If the address on the airway bill does not match the address on the PPQ Form 599 Red/White label then forward the package to the nearest USDA APHIS PPQ Plant Inspection Station. (All costs associated with rerouting misaddressed packages will be assumed by the permit holder.)
6. For all hand carry events, the port of entry must have received prior notice by e-mail, fax, or telephone of the arrival of the passenger including date of arrival and flight information from Headquarters, OFO, and APL. This notice communicates specific instructions to the port of entry.
7. For all hand carry events, a valid red and white PPQ Form 599 Red/White label specifying hand carry must be presented. A single PPQ Form 599 Red/White label specifying hand carry may be used for multiple specimens covered under one permit at border crossings.
8. If the permitted shipment arrives by hand carrying, in personal luggage, or by personal automobile without a hand carry authorization as specified in both the permit and the PPQ Form 599 Red/White label, seize the shipment and forward it to the nearest USDA APHIS PPQ Plant Inspection Station.
9. For questions or concerns, contact the USDA APHIS PPQ Permit Unit in Riverdale, MD, at 866-524-5421.

INSTRUCTIONS TO USDA PPQ INSPECTORS AT PLANT INSPECTION STATIONS:

If any of the following are not met, DO NOT CLEAR THE SHIPMENT. Contact the headquarters Permit Unit at 866-524-5421 to determine subsequent action.

1. Confirm that the package contents are listed on the permit.
2. Confirm that the shipment has the original PPQ Form 599 Red/White label with the permit number and label number visible on the exterior of the package.
3. If the PPQ Form 599 Red/White label is absent (the label may have become detached during shipping) altered or otherwise illegible, then proceed to step 14 below.
4. Confirm that the PPQ Form 599 Red/White label is addressed to your Plant Inspection Station Address.
5. Confirm that the delivery address on the package matches the address on the PPQ Form 599 Red/White label.
6. Confirm that the permit number on PPQ Form 599 Red/White label matches the actual permit number.
7. If the PPQ Form 599 Red/White label has a barcode, scan the barcode, or enter the permit number and label number into ePermits and log the required shipment information. If the PPQ Form 599 Red/White label does not have a barcode, validate the permit using the ePermits search feature. (The

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ePermits system only validates permits issued within ePermits.)

8. Confirm that the permit has not expired.

9. Confirm that the final destination of the package is to the same individual and address that appears on the permit.

10. Confirm that the origin of the shipment is authorized on the permit.

11. Use a biosafety cabinet to inspect shipments of microorganisms.

12. Confirm that the package is adequate to prevent escape of the enclosed organisms.

13. If all permit conditions are met, release the package for subsequent movement to the permit holder's address.

14. Do not open the package outside of a biosafety cabinet.

- If your facility does not have a biosafety cabinet and the package is secure, re-export the package.
- If your facility does not have a biosafety cabinet and the package is not secure, destroy the package.
- If your facility has a biosafety cabinet, examine the contents for a PPQ permit or enclosed supplemental label information.

- If the package contains a PPQ permit or supplemental label information, proceed to step 7 above.

(Supplemental label information includes the permittee's letterhead stationary with their name, permit number and label number. This information enables you to use the ePermits barcoding feature if the missing label was barcoded, or validate the permit in ePermits using the search feature if the label was not barcoded.)

- If the package does not contain a PPQ permit or supplemental label information and the package is secure, re-export the shipment.

- If the package does not contain a PPQ permit or supplemental label information and the package is not secure, destroy the shipment.

PERMIT GUIDANCE

This permit does not authorize importation, interstate movement, possession, and/or use of strains of genetically engineered regulated organisms (created by the use of recombinant DNA technology).

This permit does not fulfill the requirements of other federal or state regulatory authorities. As appropriate, please contact the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, or your State's Department of Agriculture to ensure proper permitting.

If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

Receipt or use of foreign isolates or samples from countries under sanctions requires specific permission from the U.S. Department of Treasury (see <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx> for current

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country/regional listings) for current country listings.

If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_anproducts.sh

tml .

If a human pathogen is identified, please see the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>.

PERMIT CONDITIONS

This permit authorizes the importation of pure cultures of unidentified microorganisms from Germany and Mexico, for the isolation and identification of the microorganisms listed on the permit. The permit is issued to Frisby Smith of Bayer CropScience - Biologics, located at 890 Embarcadero Drive, West Sacramento, CA 95605. This authorization is strictly for microbe isolation and identification in a controlled laboratory environment. Plant and animal inoculations, and field research are not authorized under this permit (separate permits are required for such activities). Experiments with the regulated materials must be carried out in the inspected facility # 3279.

This permit authorizes the chemical and/or physical analysis procedures (including isolation of nucleic acids), typically authorized under a separate PPQ Form 525 permit, only if the operating procedures on file addressed those uses.

All operations must be consistent with information submitted in association with the above listed APHIS facility number.

1. The regulated material must be packaged for importation in a securely closed, watertight primary container (e.g., test tube, vial, or ampule) that is completely enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container. The space between the primary and secondary containers must contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers must be enclosed in an outer shipping container constructed of corrugated fiberboard, corrugated cardboard, wood, or other material of equivalent strength.

All samples will be mailed/shipped directly to the permit holder.

You must instruct senders of the regulated material to double seal samples in heavy plastic bags (e.g. two zip-lock freezer bags), and to place the sealed bags in sturdy shipping container (e.g., Kraft paper or plastic shipping tubes/boxes).

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2. All packages must be opened within a laminar flow biosafety cabinet (Class II, Type A) . All isolations and culture transfers must be made in this biosafety cabinet.
3. All packing materials, shipping boxes, etc., which contained or were associated with the regulated material, must be sterilized or destroyed immediately after removing the regulated materials.
4. While in storage, all regulated material and cultures will be kept locked (e.g. in freezer, cabinet), with access limited to authorized personnel or they will be in a restricted access building that requires a key card entry and access is restricted to authorized personnel only; or it will be in locked room restricted to authorized personnel only.
5. The permit holder or authorized individual must notify APHIS Plant Protection and Quarantine (PPQ) Pest Permitting Branch (PPB) within 10 working days of the confirmation that an organism is identified as (a) a species new to science, (b) an organism not known to occur in the United States, (c) a pathogen managed by an APHIS program (program pest; http://www.aphis.usda.gov/plant_health/plant_pest_info/index.shtml), or (d) a pathogen in which the contained facility is located (http://www.aphis.usda.gov/plant_health/permits/organism/wpp/index.shtml). Include the permit number, the origins and dates of receipt of the samples, and the identified organism. The notification must be sent to USDA/APHIS/PPQ/RPM/PPB, 4700 River Rd., Unit 133, Riverdale, MD 20737, faxed to 301-734-8700 or emailed to Pest.Permits@aphis.usda.gov Attn: Osmond Baron, as Word, Excel or pdf documents. Notifications must also be sent to the State Plant Health Director (SPHD) and State Plant Regulatory Official (SPRO) (of the state of origin of the specific sample) within 10 working days (see http://www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml and <http://www.nationalplantboard.org/member/index.html> for contact information).

Plant pathogens isolated from materials received under this permit may be retained for laboratory use, if all of the following are met: (a) notification is provided to USDA-APHIS PPQ within ten days of confirmed identification of the organism(s), (b) a PPQ 526 application for research with the named organism(s) is received within 48 hours of the notification (section a), and (c) the organism is not listed as a program pest or a quarantine pest.

Applicant must have valid permits to maintain biocontrol organisms isolated from imported soils, plant material, or other sources.

6. (a) Adequate protective clothing must be worn when working with the regulated material and infected/infested samples so that movement of plant pests out of the facilities on hands, shirts, pants, and shoes does not occur.
- (b) Laboratory flooring materials must be monolithic and consist of building materials that can be cleaned. Flooring materials must be maintained free of soil and defects that allow growth or survival of soil-borne pests.
- (c) Work benches must consist of building materials that can be cleaned, and are maintained free of defects that allow growth or survival of soil-borne pests.

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- (d) Disposable blotter materials used on workbench surfaces must autoclaved after each position of work is completed. Work surfaces must be appropriately cleaned between samples to reduce the potential for survival of soil-borne pests.
- (e) All source materials must be heat or chemically treated, on-site, sufficient to kill or render non-viable all life stages prior to disposal in municipal sewer or waste systems.
- (f) Any sink / laboratory water that may contain live nematode life stages (wastewater), infested soil, infested growing media, and infected plant materials (waste) must be equipped with traps that allow collection of waste water, and subsequent treatment of this wastewater kills or destroys all nematode life stages on-site prior to disposal in municipal sewer or waste systems.
7. Upon completion of the isolation and identification activities, all soil, infected plant material, and all cultures derived from these materials must be destroyed by autoclaving. Glassware and other materials used to conduct research must be decontaminated prior to reuse or disposal. These materials can either be (a) soaked in a fresh solution of 10 percent bleach (1:10v/v) for at least 30 minutes, (b) saturated with 70 percent ethanol, (c) flamed with ethanol, or (d) treated with quaternary ammonium compounds, until all microorganisms are dead or non-viable.
8. Autoclaving Waste
- a. Waste must be autoclaved at 121 degrees Centigrade (250 degrees Fahrenheit) for a minimum of 30 minutes.
- b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
- c. The autoclave must be professionally calibrated annually and a written record must be maintained.
- d. Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores (e.g. Geobacillus species) that are rendered unviable at 121 degrees C. You must follow the manufacturers instructions. If any growth is observed, you must have the autoclave serviced and retested.
9. All necessary precautions must be taken to prevent the escape of the regulated material.
- Plant and animal inoculations, and field research of plant pests or biocontrol organisms are not authorized under this permit (separate permits are required for such activities).
10. Vector transmission is NOT permitted under this authorization.
11. All persons working with these organisms must be informed of these permit conditions. Anyone working with these organisms must agree to and sign/ initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/ APHIS but must be readily accessible in the event of an inspection and presented upon request.

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Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

12. The permit holder must:

- (a) comply with all requirements and permit conditions,
- (b) maintain a valid permit so long as the regulated organisms are alive,
- (c) not assign or transfer this permit to other persons,
- (d) safeguard and dispose of the regulated organisms during the term of this permit,
- (e) take all necessary precautions to prevent the unauthorized release of regulated organisms. In the event of an unauthorized release, the permit holder must notify the permit unit,
- (f) adequately mitigate environmental impacts resulting from unauthorized release of regulated organisms,
- (g) contain any/all organisms not authorized under this permit,
- (h) notify the permit unit of the receipt of unauthorized organisms,
- (i) notify the permit unit if facilities are destroyed or decommissioned for any reason,
- (j) maintain an official permanent work assignment at the address on this permit,
- (k) notify the permit unit in advance of any change in the permit holder's work assignment,
- (l) destroy all regulated organisms prior to departure from the organization unless other arrangements are confirmed by the permit unit prior to parting, and
- (m) notify the permit unit of the destruction of regulated organisms.


Notifications to the permit unit must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

13. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agricultural Select Agent Program (ASAP) immediately by phone at 301-851-3300, and within seven (7) days submit APHIS/CDC Form 4 (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, ASAP; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at:

http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002.

14. There is to be no further distribution of these organisms without prior approval from State and Federal regulatory officials. A valid permit is required from both sender and receiver for interstate movement of the regulated materials.

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15. Without prior notice and during reasonable hours, authorized PPQ and/or State regulatory officials shall be allowed to inspect the conditions associated with the regulated organisms authorized under this permit.
16. A copy of this permit must accompany each shipment.
17. Upon issuance of this permit (i.e., a signed PPQ 526), you will need to request the PPQ Form 599 Red/White labels at least 5 days in advance. If you applied online using ePermits, you may request the labels using the My Shipments/Labels feature. Otherwise, send your request to Redandwhitelabelrequest@aphis.usda.gov. All email requests must come from the permit holder or appointee. If requested by the appointee the permit holder must be Ccd on all requests. Specify the approved port as listed on the permit and the total number of labels needed in multiples of 4. You may request additional labels the same way.

APHIS-PPQ will send you the labels by email as a pdf. You are responsible for printing this pdf to produce your individual bar coded import labels. You may email the pdf to your suppliers for them to print and attach to the shipment. You or your suppliers must print all labels in color. Failure to do so may result in refused entry or destruction of your package.


A label must be attached with clear tape to the exterior of each package being imported under this permit. The labels will include detailed shipping instructions. You are responsible for instructing your shipper to carefully follow these instructions. You are responsible for each import shipping label issued under this permit.

Enclose the following supplemental information in each shipment:

- Permittee Name
- Permit number
- Label number

Underlying packaging/wrapping must carry the address, billing, and any other information required to direct the shipment to its final destination (i.e., the permit holder's address; N.B., USDA APHIS does not defray any additional shipping costs incurred for transiting the shipment through an inspection station as the initial US destination).

18. Hand-carry of the regulated material is not authorized under this permit.
19. Failure to comply with the terms and conditions of this permit may be cause for: (a) cancellation of this permit; (b) cancellation of other valid permits issued to the individual named as the holder of this permit; (c) seizure and destruction of permitted organisms; (d) denial of future permit applications made by the holder of this permit; (e) making the holder of this permit liable for civil penalties; and (f) subjecting the holder of this permit to criminal prosecution as provided in the Plant Protection Act

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END OF PERMIT CONDITIONS

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